PATENT
ATTY. DOCKET NO. /LF-227

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte Hynes

Appeal No. _____

Serial No.:	10/811,258
Filed:	March 26, 2004
Group Art Unit:	3763
Examiner:	Elizabeth MacNeill
Applicant:	Michael R. Hynes
Title:	CALIBRATED PUSHROD FOR INJECTION VOLUME CONTROL IN PREFILLED SYRINGES

Cincinnati, Ohio 45202

January 30, 2009
Via EFS-WEB

APPEAL BRIEF

This brief is in furtherance of Applicant's Notice of Appeal filed October 30, 2008, appealing the decision of the Examiner dated July 30, 2008 finally rejecting claims 1-11. A copy of the claims appears in the Appendix to this brief.

Certificate of Electronic Transmission

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/ Thomas W. Humphrey / January 30, 2009
Thomas W. Humphrey Date
Reg. No. 34,353

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Real Party In Interest

The real party in interest in this appeal is Mallinckrodt Inc., a corporation of Delaware having a place of business at 675 McDonnell Boulevard, St. Louis, MO 63134.

Related Appeals and Interferences

There are no such appeals or interferences.

Status of Claims

Total Number of Claims in the Application

Claims in the application are 1-11:

Status of all the Claims

1. Claims cancelled: NONE
2. Claims withdrawn from consideration but not cancelled: NONE
3. Claims objected to: NONE
4. Claims allowed or confirmed: NONE
5. Claims rejected: 1-11

Claims on Appeal

The claims on appeal are Claims 1-11.

Status of Amendments

There are no amendments pending.

Summary of Claimed Subject Matter as to Independent Claim 1

Subject matter within the scope of independent Claim 1 is described in the specification starting at page 4, line 13, and Fig.1, reference numbers 14 (pushrod), 28 (shaft), 24 (volume markers), and 30 (stop) in the drawings.

As explained in the specification at page 6, lines 1-5, a prefilled syringe of a specific volume, includes a pushrod 14 with a shaft that carries a scale (e.g., volume markers 24) that is calibrated to the size of the prefilled syringe 12. The stop 30 is moved along the shaft and located using the volume markers 24 in correspondence to a prescribed dosage to be injected from the prefilled syringe.

Summary of Claimed Subject Matter as to Independent Claim 6

Subject matter within the scope of independent Claim 6 is described in the specification starting at page 4, line 13, and Fig.1, reference numbers 14 (pushrod), 28 (shaft), 24 (volume markers), and 30 (stop) in the drawings.

As explained in the specification at page 6, lines 1-5, a prefilled syringe of a known volume, includes a pushrod 14 with a shaft that carries a scale (e.g., volume markers 24) that is calibrated to the size of the prefilled syringe 12. The stop 30 is movable along the shaft and located using the volume markers 24 in correspondence to a prescribed dosage to be injected from the prefilled syringe.

Summary of Claimed Subject Matter as to Independent Claim 11

Subject matter within the scope of independent Claim 11 is described in the specification starting at page 4, line 13, and Fig.1, reference numbers 14 (pushrod), 28 (shaft), 24 (volume markers), and 30 (stop) in the drawings.

As explained in the specification at page 6, lines 1-5, a method of injective fluid from a prefilled syringe of a specific volume, involves coupling a pushrod 14 to the syringe, where the pushrod has a shaft that carries a scale (e.g., volume markers 24) that is calibrated to the size of the prefilled syringe 12. A stop 30 on this pushrod is moved along the shaft and relative to the volume markers 24 to a prescribed dosage, and then the dosage is injected as noted at page 6, lines 16-21.

Grounds of Rejection

Claims 1-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Travalent et al (US 4,246,898).

Claims 1-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Blackman (US 4,466,426).

Argument

The present invention is directed to a prefilled syringe with a calibrated plunger, and methods of use thereof. The plunger is calibrated with accurate volumes because it is known how much fluid is filled into the syringe.

Specifically, the present claims recite a syringe containing "a known volume of medical fluid" (see claims 1 and 6) or a "known amount contained [in the syringe]". The plunger pushrod and calibrated scale are recited as a "scale corresponding to the known volume of the prefilled syringe" (claim 1), or "a scale calibrated to the known amount contained in the prefilled syringe". Because the amount in the syringe is known, the scale on the pushrod can be calibrated to identify the injected amount accurately.

A prefilled syringe of the kind noted, is distinctly different from a syringe that is intended to be filled by the user prior to its use, because in the latter case there is not a "known amount" in the syringe, and therefore it is not possible for the scale on the pushrod to be calibrated for a known amount.

Argument - Rejections under 35 U.S.C. § 102 - Travalent

The Examiner relies for anticipation, upon Travalent, U.S. Patent 4,246,898.

The Travalent patent shows a syringe that is filled to any number of volumes. Although there are indicia on the Travalent plunger, these assume a particular filled volume. As can be seen in the Travalent patent at Fig. 1, the plunger 22 bears numerical indicia "0", "1", "2" and so on. Travalent explains that one can set the ring 56 at a desired number such as 3, and push the

plunger until the ring 56 contacts the ledge 24 to inject fluid. However, in order for the numerical indicia on the plunger shaft to be meaningful, the syringe must be filled so that the "0" is positioned at the ledge 24 on the rear end of the syringe barrel 12. Only in this case, will 1 unit be injected when the ring 56 is at the "1", and so on. If the syringe is not filled to a known volume, the numerical indicia on the plunger shaft will not accurately identify an injected amount.

It will be noted that Travalent's Fig. 1 clearly depicts a syringe that is overfilled – that is, the "0" on the plunger is not lined up with the ledge 24 but rather is extended well beyond the ledge 24. In this case, an injection performed using the ring 56 and plunger numbers will be oversize. A similar situation will occur if the syringe is underfilled.

Applicant submits that the basic problem of accurate filling, is not dealt with by Travalent. Indeed, Travalent is clearly not directed to a pre-filled syringe. In fact, Travalent's figures specifically illustrate the problem of a syringe that is filled with an uncalibrated amount of fluid.

In contrast, the present invention is directed to "pre-filled syringes" that have plunger indicia that are calibrated to a known pre-filled volume. The prior art does not show such a syringe nor suggest the use of pre-filled syringes that bear such indicia.

In the Examiner's Final Action, the Examiner has replied to the argument stated above, with the remark that "syringes have a known diameter ... this diameter is taken into account when selecting the scale of the plunger". What the Examiner submits may or may not be so, but it does not respond to the basic problem that, whatever scale is on the plunger, the syringe has to be filled properly, so that the "0" on the scale aligns with the back of the syringe, in order for the numbers

on the scale to accurately identify the amount of fluid injected. Unless the syringe is properly filled, the scale on the plunger shaft cannot be accurate.

Argument - Rejections under 35 U.S.C. § 102 - Blackman

In the Final Action, the Examiner has cited a new reference, Blackman U.S. Patent 4,466,426. Blackman is also not relevant to the claimed invention. Blackman shows a plunger with circumferential grooves that are called "measuring grooves". The grooves do not indicate a specific volume, but rather merely subdivide the throw of the plunger into increments of, e.g., 10 cc or the like.

The presently rejected claims recite a shaft that has a "scale" on it, and that the scale is calibrated or corresponds to the "known" amount prefilled into the syringe. Blackman has no scale on his plunger, and cannot meet these recitations. Blackman is less relevant, in fact, than Travalent for this reason. Also, Blackman does not have a "stop" as the present claims recite. Blackman shows a detent 36 that clicks into the grooves to provide audible/tactile feedback at each groove. The Examiner asserts that 36 is a stop but it is clearly not something that stops the plunger. Even the later Fig. 4 embodiment in Blackman, which has a "clip", does not appear to block movement of the plunger, rather, that embodiment apparently only provides a click or other feedback when the plunger is moved to one of the measuring grooves. Thus, in this respect as well, Blackman's disclosure is not relevant to the claimed invention.

In order for a reference to anticipate a claimed invention, the reference must teach each and every element in the precise arrangement set forth in the claim. See MPEP § 2131. If the reference fails to teach even one of the claimed features, the reference does not and cannot anticipate the claimed invention. Based on the deficiencies of Travalent and Blackman identified above, Applicant respectfully requests that the rejections for claim 1, 6 and 11, and claims 2-5 and 7-10 which depend therefrom, be withdrawn.

Accordingly, Applicant submits that the Examiner's rejection is in error and a reversal of the rejection and allowance of the claims is therefore requested.

A petition for extension of time is necessary to accompany this communication, please consider this paper a petition for such an extension of time, and authorization to charge a credit card will be provided in the EFS-WEB transmittal. If any other charges or credits are necessary to complete this communication, please apply them to Deposit Account 23-3000.

Respectfully submitted,

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Claim Appendix

1. (previously present) A pushrod for use with a prefilled syringe containing a known volume of a medical fluid, comprising:

a shaft including a scale corresponding to the known volume of the prefilled syringe; and,

a stop movable relative to the scale and configured for location along the shaft;

the stop located using the scale in correspondence with a prescribed dosage injected from the prefilled syringe.

2. (original) The pushrod of claim 1, the shaft and the stop including corresponding threads, the threads used for locating the stop along the shaft.

3. (original) The pushrod of claim 1, the shaft including a thumb rest.

4. (original) The pushrod of claim 1, the shaft made of a molded material.

5. (original) The push rod of claim 1, the prefilled syringe including a barrel with a flange, the stop abutting the flange when the prescribed dosage has been injected.

6. (previously present) A hand-held syringe assembly comprising:

a prefilled syringe containing a known volume of a medical fluid; and,

a pushrod configured for use with the prefilled syringe and including:

a shaft having a scale corresponding to the known volume of the prefilled syringe; and,

a stop movable relative to the scale and configured for location along the shaft;

the stop located using the scale in correspondence with a prescribed dosage injected from the prefilled syringe.

7. (original) The assembly of claim 6, the shaft and the stop including corresponding threads, the threads used for locating the stop along the shaft.

8. (original) The assembly of claim 6, the shaft including a thumb rest.

9. (original) The assembly of claim 6, the shaft made of a molded material.

10. (original) The assembly of claim 6, the prefilled syringe including a barrel with a flange, the stop abutting the flange when the prescribed dosage has been injected.

11. (previously present) A method of injecting a medical fluid from a prefilled syringe containing a known amount of medical fluid, comprising:

coupling a calibrated pushrod to the prefilled syringe, the pushrod having a scale calibrated to the known amount contained in the prefilled syringe;

setting a stop on the pushrod to a prescribed dosage wherein the setting comprises moving the stop relative to a scale on the pushrod; and,

administering the dosage through injection.

Evidence Appendix

None.

Related Proceedings Appendix

None.